CONTINUOUS GLUCOSE MONITORS

Revised October 2024

Dear Clinician,

Medicare covers certain continuous glucose monitor (CGM) devices under the Durable Medical Equipment (DME) benefit. The following information is intended to provide you with summary guidance on Medicare's coverage criteria and documentation requirements for a CGM device and related CGM supplies allowance is available for CGM systems when the beneficiary uses a stand-alone receiver or insulin infusion pump to display glucose data. In addition, Medicare coverage is available for a CGM system supply allowance if a non-DME device (watch, smartphone, tablet, laptop computer, etc.) is used in conjunction with the durable CGM receiver. The following are examples of this provision:

1. Medicare coverage of a CGM supply allowance is available when a beneficiary uses a durable CGM receiver to display their glucose data and also transmits that data to a caregiver through a smartphone or other nonDME receiver.
2. Medicare coverage of a CGM system supply allowance is available when a beneficiary uses a durable CGM receiver on some days to review their glucose data but uses a non-DME device on others.

If a beneficiary never uses a DME receiver or insulin infusion pump to display CGM glucose data, then Medicare does not cover the supply allowance.

INITIAL COVERAGE

CGMs and related supplies are covered by Medicare when all of the following initial coverage criteria (1-5) are met:

1. The beneficiary has diabetes mellitus; and,

2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and,

3. The CGM is prescribed in accordance with its FDA indications for use; and,

4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:

    a. The beneficiary is insulin-treated; or,

b. The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
- A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.

5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicareapproved telehealth visit with the beneficiary to evaluate their diabetes control and determine that criteria (1-4) above are met.

If the CGM functions in conjunction with an external insulin infusion pump (i.e., if the CGM is integrated into an external insulin infusion pump), then the coverage criteria for the external insulin infusion pump must be met in addition to the CGM coverage criteria (1-5) above. (Please refer to the External Infusion Pumps Local Coverage Determination (LCD) (L33794) for insulin infusion pump coverage requirements.)

When a CGM is covered, the related supply allowance is also covered.

CONTINUED COVERAGE

In order for Medicare to continue covering CGMs and related supplies, every six (6) months following the initial prescription of the CGM, the treating practitioner must have an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their CGM regimen and diabetes treatment plan.

MEDICAL NECESSITY DOCUMENTATION

For the in-person or Medicare-approved telehealth treating practitioner visit required as part of the initial provision of a CGM, sufficient information must be in the beneficiary's medical record to determine that the initial coverage criteria have been met.

For initial coverage criterion 4B, the treating practitioner's medical record must document that the beneficiary has a history of problematic hypoglycemia consistent with one of the following pathways to coverage:

1. Beneficiaries with non-insulin-treated diabetes and a history of recurrent (more than one) level 2 hypoglycemic events
   a. The treating practitioner must document at least one of the following in the medical record for each event:

i. The glucose values for the qualifying event(s) (glucose <54mg/dL (3.0mmol/L)); or,

ii. Classification of the hypoglycemic episode(s) as level 2 event(s); or,

iii. Incorporate a copy of the beneficiary's BGM testing log into the medical record reflecting the specific qualifying events (glucose <54mg/dL (3.0mmol/L)); and,

b. Documentation of more than one previous medication adjustment and/or modification to the treatment plan (such as raising A1c targets) prior to the most recent level two event.

2. Beneficiaries with non-insulin-treated diabetes and a history of at least one level 3 hypoglycemic event

a. The treating practitioner must document at least one of the following in the medical record:

i. The glucose value for the qualifying event (glucose <54mg/dL (3.0mmol/L)); or,

ii. Classification of the hypoglycemic episode as a level 3 event; or,

iii. Incorporate a copy of the beneficiary's BGM testing log into the medical record reflecting the specific qualifying event (glucose <54mg/dL (3.0mmol/L)); and,

b. An indication in the medical record that the beneficiary required third party assistance for treatment.

For the in-person or Medicare-approved telehealth treating practitioner visit required as part of the ongoing provision of a CGM, sufficient information must be in the beneficiary's medical record to determine that the continued coverage requirements have been met.

SUPPLIES FOR CGM DEVICES

Medicare pays a supply allowance for supplies used with a covered CGM system. The supply allowance (code A4238 or A4239) is a monthly allowance that may be billed up to a maximum of three (3) units of service (UOS) per ninety (90) days at a time and suppliers may not dispense more than a ninety (90) day supply. Sufficient supplies must be provided to the beneficiary to last for at least thirty (30) days of therapy.

The supply allowance for a non-adjunctive CGM encompasses all items necessary to use the device. Items deemed necessary for the use of the non-adjunctive CGM device include, but are not limited to: CGM sensors, CGM transmitters, home BGM and related supplies (test strips, lancets, lancing device, calibration solution, and batteries).

The supply allowance for an adjunctive CGM encompasses all items necessary to use the device. Items deemed necessary for the adjunctive CGM device include, but are not limited to, CGM sensors and transmitters. The supply allowance for an adjunctive CGM device does not

include the BGM and BGM testing supplies (test strips, lancets, lancing devices, calibration solutions, and batteries).

This article is intended to be a general summary. It is not intended to take the place of the written law, regulations, national coverage determinations (NCDs), or LCDs. Coverage, coding, and documentation requirements for CGM devices and related supplies may be found in the Glucose Monitors LCD (33822) and LCD-related Policy Article (A52464), located in the Medicare Coverage Database.

Sincerely,

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